PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Paul C. Anderson et al.

Serial No.: 09/732,439

Filed: December 7, 2000

For: TRANSGENIC MAIZE WITH INCREASED PROLINE CONTENT (AS AMENDED)

Group Art Unit: 1638

Examiner: Cynthia E. Collins

Atty. Dkt. No.: DEKM:184USD1

CERTIFICATE OF ELECTRONIC SUBMISSION

Date of Submission: October 31, 2006

REQUEST FOR REHEARING UNDER 37 C.F.R. §41.52

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Appellants hereby submit this Request Rehearing Under 37 C.F.R. §41.52 responsive to the Decision on Appeal mailed in the case on August 31, 2006. The deadline for filing this Request is October 31, 2006. No fees are believed due in connection with this submission. However, the Commissioner is authorized to deduct any fees that may become due under 37 C.F.R. §§ 1.16 to 1.21 from Fulbright & Jaworski, L.L.P. Account No. 50-1212/DEKM:184USD1.

GROUNDS FOR REQUEST

I. REQUEST FOR RELIEF

A. Rehearing is Warranted Under 37 C.F.R. §41.52(a)(2)

Rehearing of this case is respectfully requested on the basis that a recent decision of the Court of Appeals for the Federal Circuit impacts the outcome of the Board's decision on appeal. Specifically, as described further below, the written description rejection of claims 59-63, 72 and 73 should not have been affirmed in view of the opinion of the Court of Appeals for the Federal Circuit in *Capon v. Eshhar*, 418 F.3d 1349, 1359-1360 (Fed. Cir. 2005).

Appellants did not earlier present this issue because *Capon v. Eshhar* was decided subsequent to all briefing in this case. Appellants' Appeal Brief was filed on March 12, 2004, an Examiner's Answer was mailed March 28, 2005, and Appellants' Reply Brief was filed May 31, 2005. *Capon v. Eshhar* was decided on August 12, 2005.

B. Prayer for Relief

Rehearing is respectfully requested under 37 C.F.R. §41.52 because the affirmance by the Board of the written description rejection of claims 59-63, 72 and 73 is legally inconsistent with the holding of *Capon v. Eshhar*. Rehearing and reversal of the rejection is thus respectfully requested. Reversal is also requested based on the failure of the Examiner to properly consider the level of skill in the art when analyzing the written description rejection.

II. GROUNDS FOR REHEARING AND REVERSAL

A. Brief Summary of Decision on Appeal

The Decision on Appeal reversed the rejection of claims 61-63 under 35 U.S.C. §112, second paragraph; the rejection of claims 59-61, 63, 72 and 73 under 35 U.S.C. §102(e); and the rejection of claims 59-63, 72 and 73 under 35 U.S.C. §103. The Board did not reach the merits

of the rejection of claims 59-63, 72 and 73 under the enablement provision of 35 U.S.C. §112, first paragraph. Finally, the Board affirmed the rejection of claims 59-63, 72 and 73 under 35 U.S.C. §112, first paragraph for an alleged lack of adequate written description. This written description rejection should be reversed as set forth below.

B. The Decision Was Improperly Predicated on the Holding of *Eli Lilly*

The Board relied extensively on the holding in *University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997) in affirming the written description rejections of the Examiner. For example, the Decision on Appeal affirmed the written description rejection on the basis that the specification did not adequately disclose DNA sequences encoding an enzyme catalyzing the synthesis of the osmoprotectant proline. In particular, the Board took issue with the fact that specific nucleotide sequences were not listed in the specification, stating that:

> [A]ppellant's specification fails to provide a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the claimed genus. Since the specification does not describe the claimed DNAs adequately for those skilled in the art to distinguish the claimed DNAs from other DNAs, the specification does ***not adequately describe the claimed DNAs under the standard of Eli Lilly.***

Decision on Appeal, p. 11 (emphasis added).

In the sections preceding this portion of the decision, extensive quotations are made to *Lilly*, for example, stating the "[w]hen faced with circumstances similar to those at issue here, our appellate reviewing court has held claims to lack adequate written description." Decision at p. 9, *quoting Lilly*. The decision continues, noting that "[t]he *Eli Lilly* court held that a fully described genus is one for which a person skilled in the art can "visualize or recognize the identity of the members of the genus." *Id.*

It is thus clear that the written description analysis was based on the *Lilly* standard. In its analysis, however, the Board failed to acknowledge that the facts and holding of *Lilly* are

inapposite to the present case, as vividly demonstrated in *Capon*. Unlike the present case, *Lilly* concerned a gene that "had never been characterized." *See Capon v. Eshhar*, 418 F.3d 1357, 1359 (Fed. Cir. 2005). In *Lilly*, the subject patent claimed a novel human insulin-encoding cDNA sequence but disclosed only a rodent sequence. A lack of adequate written description was found because the specification failed to describe the very human sequence being claimed. *Lilly*, 119 F.3d at 1568. That is, what was allegedly not described was precisely the point of novelty of what was being claimed. It is therefore not surprising that the Federal Circuit held that this subject matter must be described with a degree of particularity and that written description was lacking when it was not.

In contrast, the current application does not claim nucleic acids and the novelty of the invention does not turn on the DNA sequences allegedly non-disclosed, which were known in the art. Rather, the invention lies in the expression of known DNA sequences in a monocot plant to confer drought tolerance. As explained more fully below, the Federal Circuit has held that it is improper to apply the *Lilly* holding in such a situation, and rather the correct legal standard is set forth by *Capon*.

C. The *Capon* Holding Requires Reversal of the Written Description Rejection

Capon involved an appeal to the Federal Circuit from a Board decision holding that all claims at issue in an interference were invalid for lack of written description. *Capon*, 418 F.3d at 1354-55. The Board summarized its findings by stating:

> Here, both Eshhar and Capon claim novel genetic material described in terms of the functional characteristics of the protein it encodes. Their specifications do not satisfy the written description requirement because persons having ordinary skill in the art would not have been able to visualize and recognize the identity of the claimed genetic material without considering additional knowledge in the art, performing additional experimentation, and testing to confirm results.

Id. at 1355. As can be seen, this standard is almost verbatim that recited in the current Board decision section at page 9, which tracks that of *Lilly*. It therefore appears that the Board applied reasoning in *Capon* that is the same as used in the decision at issue here.

The Federal Circuit disagreed with this characterization of the claims, noting that the "genes here at issue are prepared from known DNA sequences of known function." *Id.* at 1358. The *Capon* court also noted that the "invention is not in discovering which DNA segments are related to the immune response, for that is in the prior art, but in the novel combination of the DNA segments to achieve a novel result." *Id.*

The court contrasted this with *Lilly*, noting that "[i]n *Lilly*, the cDNA for human insulin had never been characterized." *Id.* at 1357 (citation omitted). The *Capon* panel found this distinction to be significant, stating that "[t]he written description requirement must be applied in the context of the particular invention and the state of the knowledge." *Id.* The *Capon* panel further noted "[t]he Board's rule that the nucleotide sequences of the [claimed] genes must be fully presented, although the nucleotide sequences of the component DNA are known, is an inappropriate generalization." *Id.* at 1358. The court therefore reversed the Board rejection for lack of written description, and concluded:

> The Board's requirement that these sequences must be analyzed and reported in the specification does not add descriptive substance. **The Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes**.

Id. (emphasis added).

The present case involves issues that are more analogous to those in *Capon*, rather than those in *Lilly*. As in *Capon*, Applicants are not claiming novel nucleic acids, but rather are claiming an invention that makes use of known sequences. The Board acknowledges in the present case that at least two genes for use with the invention were

known, but nonetheless applied the *Lilly* standard to assert that "a recitation of a representative number of cDNAs, defined by nucleotide sequence" was not provided as allegedly required. When faced with facts similar to those in the present case, the *Capon* court concluded:

> The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge. The Board's rule that the nucleotide sequences of the chimeric genes must be fully presented, although the nucleotide sequences of the component DNA are known, is an inappropriate generalization. When the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh.

Capon, 418 F.3d at 1358.

It is therefore improper to apply the standard set forth in *Lilly* to the facts of the present case. The case at issue does not include claims directed toward a novel gene, and therefore should not require sequence listings in the specification to satisfy the written description requirement. Because the Board applied an improper legal standard to the facts of this case, the rejection of claims 59-63, 72 and 73 based on lack of written description should be reversed and such action is thus respectfully requested.

D. Additional Reference Should Be Considered

Although not mandatory for a reversal of the Examiner's written description rejection, Appellants believe that the Board improperly failed to consider an additional reference indicative of the level of skill in the art at the time the invention was made. For example, the Decision on Appeal noted that the Examiner did not consider a reference by Williamson *et al.* because it was allegedly not made of record[1]. However, under §112 it is specifically the burden of the

[1] *See* footnote 2, page 11 of the Decision on Appeal. The Board did not consider Williamson *et al.* (Williamson), "Molecular Cloning and Evidence for Osmoregulation of the Δ1-Pyrroline-5-Caroboxylate Reductase (proC) Gene in Pea (Pisum sativum L.)," Plant Physiol., Vol. 100, pp. 1464-1470 (1992) based on the Examiner's assertion that the reference was not properly made of record in the application.

Examiner to determine the level of skill in the art. As stated in the Manual of Patent Examining Procedure (MPEP):

> The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is ***conducted from the standpoint of one of skill in the art at the time the application was filed and should include a determination of the field of the invention and the level of skill and knowledge in the art.***

MPEP §2163 (citations omitted) (emphasis added). This is consistent with *Capon*, which notes that "[t]he written description requirement must be applied in the context of the particular invention and the state of the knowledge." *Id.* Under §112 it is of course also the burden of the Examiner to establish a lack of patentability, rather than the burden of Applicants to prove compliance with the statute. Therefore, the Examiner in this case was ***obligated*** to take into account the level of skill and knowledge in the art. Williamson *et al.* was published prior to the effective filing date and demonstrates the contemporaneous knowledge of those of skill in the art by disclosing a gene encoding an enzyme synthesizing production of proline (specifically, a pyrroline-5-carboxylate reductase from pea). This reference, in addition to the numerous other references cited in the Appellants' Appeal Brief disclosing genes encoding enzymes biosynthesizing proline, demonstrates the high level of knowledge and skill in the art. In this context, Appellants' disclosure satisfies the standard set forth in *Capon* and the written description rejection is improper.

While the Board is not required to consider references that were not before the Examiner, it is required to determine whether the Examiner applied the correct legal standards and these standards in fact required the Examiner to analyze written description against the backdrop of the knowledge and skill level in the art. This is amplified by the holding of *Capon*, which specifically reversed the Board for failing to adequately take into account the contemporaneous

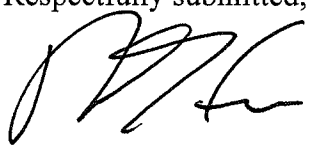
knowledge in the art. The fact that a specific reference was not of record does ***not*** change the fact that the reference was known at the time of filing of the application. Therefore, the reference is pertinent to an evaluation of the written description requirement and must be considered. Such action is thus respectfully requested

III. CONCLUSION

Appellants believe the standard set forth in *Lilly* was improperly applied by the Board in affirming the Examiner's rejection of claims 59-63, 72 and 73 under the written description provision of 35 U.S.C. §112. Appellants believe the proper standard is set forth in *Capon* for the reasons summarized above and that this standard requires reversal of the written description rejection. Accordingly, it is respectfully submitted that the Board's affirmance of the Examiner's rejection of claims 59-63, 72 and 73 for lack of written description was improper.

Appellants respectfully request that the Board reconsider and reverse the rejection of claims 59-63, 72 and 73 under the written description provision of 35 U.S.C. §112 consistent with the holding in *Capon*.

Respectfully submitted,



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